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Sertifikaat

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the documents annexed hereto are true copies of:

Application Form P1 and P2, provisional specification and drawings of South African Patent Application No. 2002/5373 as originally filed in the Republic of South Africa on 5 July 2002 in the name of TALJAARDT, Andre Johan for an invention entitled: "MEDICAL TUBE RETAINING DEVICE".

Geteken te
Signed at

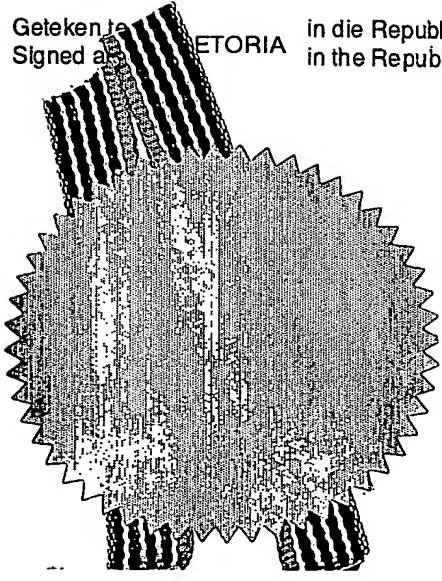
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dag van
day of

October 2003



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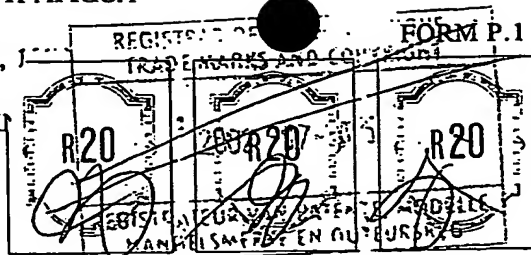
PATENTS ACT, 1977

REGISTERED TRADEMARKS AND COPYRIGHTS FORM P.1

APPLICATION FOR A PATENT AND ACKNOWLEDGEMENT

(Section 30(1) Reg)

THE GRANT OF A PATENT IS HEREBY REQUESTED BY THE UNDERSIGNED IN THE PRESENT APPLICATION FILED IN DUPLICATE



(in duplicate)

IS OF THE

21	01	PATENT APPLICATION NO: 2002/5373
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71	FULL NAME(S) OF APPLICANT(S)
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54	TITLE OF INVENTION
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Medical tube retaining device

☐ THE APPLICANT CLAIMS PRIORITY AS SET OUT ON THE ACCOMPANYING FORM P.2. The earliest priority claimed is

Country:

No:

Date:

☐ THE APPLICATION IS FOR A PATENT OF ADDITION TO PATENT APPLICATION NO

21	01
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☐ THIS APPLICATION IS A FRESH APPLICATION IN TERMS OF SECTION 37 AND BASED ON APPLICATION NO

21	01
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THIS APPLICATION IS ACCOMPANIED BY:

- ☒ A single copy of a provisional specification of **13** pages
- ☒ Drawings of **3** sheets
- ☐ Publication particulars and abstract (Form P.8 in duplicate)
- ☐ A copy of Figure **1** of the drawings (if any) for the abstract
- ☐ An assignment of invention
- ☐ Certified priority document(s).
- ☐ Translation of the priority document(s)
- ☐ An assignment of priority rights
- ☐ A copy of Form P.2 and the specification of RSA Patent Application No

21	01
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- ☒ Form P.2 in duplicate
- ☒ A declaration and power of attorney on Form P.3
- ☐ Request for classification on Form P.9
- ☐ Request for delay of acceptance on Form P.4

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Dated this **26** day of **JUNE** 2002

André Johan Taljaardt

Signature of applicant

The duplicate will be returned to the applicant's address for service as proof of lodging but is not valid unless endorsed with official stamp

OFFICIAL DATE STAMP
REGISTRAR OF PATENTS

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REGISTER OF PATENTS

PATENTS ACT, 1978

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71	TALJAARDT, André Johan				
APPLICANTS SUBSTITUTED:				DATE REGISTERED	
71					
ASSIGNEE(S)				DATE REGISTERED	
71					
FULL NAME(S) OF INVENTOR(S)					
72	TALJAARDT, André Johan				
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61					
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PROVISIONAL SPECIFICATION

(Section 30 (1) - Regulation 28)

21	01	OFFICIAL APPLICATION NO
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51	INTERNATIONAL CLASSIFICATION
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71	FULL NAME(S) OF APPLICANT(S)
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TALJAARDT, André Johan

72	FULL NAME(S) OF INVENTOR(S)
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TALJAARDT, André Johan

54	TITLE OF INVENTION
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Medical tube retaining device

A. Taljaard

FIELD OF THE INVENTION

This invention relates to a medical tube-retaining device for holding a medical tube, such as an endotracheal tube in fixed position on the teeth of a patient near the tube insertion site.

BACKGROUND

Tubes are employed for many purposes to provide for passage of air or fluids, including gases, to and from the human body. One type of tube is an endotracheal tube, which is adapted to be inserted through the oral cavity of a patient and into the trachea to provide for the supply of fluids or gasses to the body, for the monitoring of internal conditions in the body and to provide for removal of secretions from within the body.

It is desirable to secure the endotracheal tube in place within the patient to prevent it from being inadvertently advanced into the patient or retracted from the patient's mouth after it has been properly positioned. However, it is difficult to properly secure an endotracheal tube to a patient's oral cavity to prevent these events.

Presently, adhesives are used to keep the tube positioned which are ineffective because of the presence of facial hair, oily skin, dirt, blood, etc. According to this approach of retaining a medical tube near the tube insertion site, one or more adhesive strips are applied directly over the tube and to the skin of the patient. In order to adjust the position of the tube, the adhesive strip must be removed from the skin and then reapplied in the desired location. This significantly weakens the holding strength of the adhesive, and often requires the placement of additional strips on the tube and skin to properly anchor the tube. Natural body secretions further reduce the ability of the strip to properly retain the tube.

Q. Howard

Another problem is that the endotracheal tube is usually relatively easy to deform and passes between the patient's teeth if inserted orally. It is desirable to prevent the lumen of the endotracheal tube from being obstructed by a patient's teeth when the patient attempts to bite down. Obstruction of the endotracheal tube can lead to, for example, hypoxia, or other similar conditions.

The above approaches are ineffective in protecting against possible obstruction of the tube. Bite blocks can be effective in keeping a patient's jaw open and thus prevent the teeth from clamping down on the endotracheal tube. The problem is that the bite block is yet another piece of equipment that may be inserted into the patient's mouth along with other medical apparatuses.

Other prior art devices using a clamp attached to an adhesive strip are likewise ineffective. These devices are generally applicable only for a single, specific tube size and do not effectively restrict sliding movement of the tube within the clamp.

Notwithstanding the present methods and ways, a need still exists for a better way to secure an endotracheal tube in a patient while avoiding the above stated problems.

SUMMARY OF THE INVENTION

According to one aspect of the present invention, a medical tube-retaining device for an airway preferably comprises first and second spaced-apart arms, spaced radially from a base, and a clip with clamp mounted on the base for engaging and holding the tube. Said spaced-apart arms are jointed at the base for movement between an engaged and disengaged position. The clamp is adjustable for accommodating different size tubes.

Alternatively, a medical tube-retaining device for an airway may comprise first and second spaced-apart arms, spaced radially from at least one spring loaded coil, and at least one clip with clamp mounted on a base for engaging and holding the tube. Said spaced-apart arms are positioned to force a set of dental arches away from each other for movement between an engaged and disengaged position.

Orlando

The invention may further include first and second grip retaining extensions complementarily shaped to fit onto the upper and lower teeth of a patient, attached to the distal end of the first and second spaced-apart arms. Said grip retaining extensions may include a flange and slip-resistant inner lining for frictionally engaging with the teeth of a patient. The grip retaining extensions may be in the form of a dental arch.

According to yet another preferred embodiment of the invention, adjustment means for the grip retaining extensions may include complementary locking teeth formed on each of the arms. The locking teeth have respective engaging surfaces to provide locking adjustment of the grip retaining extensions. Alternatively, the distal ends of the first and second spaced-apart arms are fixed in permanent setting within the grip retaining extensions.

According to one preferred embodiment of the invention, the said spaced-apart arms comprises a suitable recoil material for movement between an engaged and disengaged position.

According to another preferred embodiment of the invention, the clamp include a slip-resistant inner lining for frictionally engaging the tube.

According to yet another preferred embodiment of the invention, the slip-resistant inner lining is formed of rubber or plastic.

According to yet another preferred embodiment of the invention, first and second grip retaining extensions are formed on the spaced-apart arms, to facilitate engagement of the grip retaining extensions with the teeth of a patient.

Therefore, the present invention provides a medical tube-retaining device for an endotracheal tube that can secure the tube to the teeth of a patient but at the same time permits the position of the endotracheal tube with respect to the patient to be readily adjusted by a medical professional.

Q. L. L. L.

The present invention also preferably provides a retaining device that prevents obstruction of an endotracheal tube by a patient's teeth.

A retaining device according to the present invention may be used with any type of endotracheal tube, which needs to be inserted into a patient's airway via the mouth, such as a respiratory tube.

An objective of the invention is to maintain an endotracheal tube at a constant depth within the patient.

Another objective of the invention is to prevent an endotracheal tube from being obstructed by the patient's teeth.

Another objective of the invention is to take up as little mouth space as possible to allow for the insertion of additional medical instruments.

Another objective of the invention is to provide a retaining device that is easy to use for medical professionals.

A further objective of the invention is to provide a device that can be used in the operating room, the intensive care unit (ICU); the emergency room, or in any situation that requires a quick, easy, and reliable means of retaining an endotracheal tube or a catheter inserted in the patient's mouth.

Therefore, it is an object of the invention to provide a tube-retaining device which conveniently and securely retains the tube in a fixed position relative to the teeth of a patient near the tube insertion site.

It is another object of the invention to provide a tube-retaining device which includes a clip and clamp that are easily opened and closed.

It is another object of the invention to provide a tube-retaining device which restricts sliding movement of the tube within the clamp.

Dr. T. J. ...

It is another object of the invention to provide a tube-retaining device which restricts sliding movement of the spaced-apart arms within the grip retaining extensions.

It is another object of the invention to provide a tube-retaining device which includes a clamp that easily closes when the tube is placed within the clamp.

It is another object of the invention to provide a tube-retaining device which includes a clamp that easily ejects the tube when the clamp is opened.

It is another object of the invention to provide a tube-retaining device which includes a clamp that is readily adjustable to securely hold different size tubes.

An advantage of the invention is that it securely holds an endotracheal tube at a constant depth within the patient once set.

Another advantage of the invention is the prevention of obstruction of an inserted endotracheal tube in a patient.

Another advantage of the invention is that it is easy to use during the initial insertion of an endotracheal tube, any adjustment of the depth within the patient of the endotracheal tube, and the removal of the endotracheal tube.

Another advantage of the invention is that it leaves space for the insertion of additional medical instruments into the patient's mouth.

Another advantage of the invention is that it can still work when debris, blood, facial hair, dirt, perspiration and excessive soft tissue are present in the vicinity.

A further advantage of the invention is that an endotracheal tube is protected from obstruction resulting from forces being applied to it by the patient's jaw and teeth.

A further advantage of the invention is the minimization and elimination of the likelihood of inadvertent extubation or mainstem intubation.

Dr. Leonard

Further objects, advantages and features of the present invention, together with the organization and manner of operation thereof, will become apparent from the foregoing detailed description of the invention when taken in conjunction with the accompanying drawing wherein like reference numerals designate like elements throughout the several views.

BRIEF DESCRIPTION OF THE DRAWINGS

Some of the objects of the invention have been set forth above. Other objects and advantages of the invention will appear as the description proceeds when taken in conjunction with the following drawings, in which:

Figure 1 illustrates a top view of an embodiment of a retaining device according to the present invention with first and second spaced-apart arms having grip retaining extensions in an engaged position securing the retaining device to the teeth of a patient. A clip with clamp is seated upon a base to retain the tube.

Figure 2 shows a top view of a retaining device according to the present invention with first and second spaced-apart arms having grip retaining extensions in a disengaged position.

Figure 3 shows a side view in an alternative embodiment of the invention and illustrating a prototype of a medical tube-retaining device for an airway with first and second spaced-apart arms, spaced radially from spring loaded coils, and at least one clip with clamp mounted on a base for engaging and holding the tube. The spaced-apart arms are positioned to force a set of dental arches away from each other for movement between an engaged and disengaged position.

Q. Steward

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now specifically to the drawings, a medical tube-retaining device according to the present invention is illustrated in FIGS. 1, 2 and 3, and shown generally at reference numeral 1. The tube-retaining device 1 is applicable for holding a medical tube 4, in a fixed position near the tube insertion site.

A clamp 8 is attached to the retaining device 1 for holding the tube 4 as it exits the airway 3 of the patient. The clamp 8 may be integrally formed of a molded plastic material, and includes a mounting clip 7 attached to a base 6 formed by the joint of a pair of spaced-apart arms 5. The spring loaded arms 5.1 and 5.2 are connected together at a connecting base 6. The arms 5.1 and 5.2 are movable between an engaged position 9, shown in FIG. 1, and a disengaged position 10, shown in FIG. 2.

Alternatively, clamp 8 in the form of a suitable fastening means 22, is attached to the clip 7 for holding tube 4 as it exits the airway 3 of the patient 70. The fastening means 22 encircles tube 4 accordingly whereby tube 4 may be attached to base 6. Said base 6 is in fixed arrangement with dental arch 21.1. The spring loaded arms 5.1 and 5.2 may form at least one spring loaded coil 20.1. The arms 5.1 and 5.2 are movable between an engaged and a disengaged position. Ideally, spring loaded coil 20.1 is positioned to force dental arches 21.1 and 21.2 apart to maintain the jaws of a patient in an open position. It should be appreciated that a secondary spring loaded coil 20.2 may also be positioned to enhance the force applied to the dental arches 21.1 and 21.2.

The illustrated retaining device 1 preferably includes first and second spaced-apart arms 5.1 and 5.2, spaced radially from coil 20.1. A clip 7 and clamp 8 may be mounted on base 6 for engaging and holding tube 4. Base 6 may be fixed to dental arch 21.1 or any other suitable position to retain tube 4 in a fixed location. The spaced-apart arms 5.1 and 5.2 may also be jointed at the base 6 for movement between an engaged 9 and disengaged position 10.

Ar. L. L. L.

The invention may further include first and second grip retaining extensions 11.1 and 11.2 complementally shaped to fit onto the upper teeth 2.1 and lower teeth 2.2 of a patient 70, attached to the distal end 15 of the first and second spaced-apart arms 5.1 and 5.2. Said grip retaining extensions 11.1 and 11.2 may include a flange 12 and slip-resistant inner lining 13 for frictionally engaging with the teeth 2 of a patient (not shown). As stated above, said grip retaining extensions 11.1 and 11.2 may be in the form of dental arches 21.1 and 21.2.

In a further preferred embodiment of the invention, adjustment means 14 for the grip retaining extensions 11.1 and 11.2 may include complementary locking teeth (not shown) formed on each of the arms 5.1 and 5.2. The locking teeth (not shown) have respective engaging surfaces (not shown) to provide locking adjustment of the grip retaining extensions 11.1 and 11.2.

The present invention provides a medical tube-retaining device 1 for an endotracheal tube 4 that can secure the tube 4 to the teeth 2 of a patient, but at the same time permits the position of the endotracheal tube 4 with respect to the patient to be readily adjusted.

Preferably, grip retaining extension 11.1 is positioned and forced over the upper teeth 2.1 of a patient. Similarly, grip retaining extension 11.2 is positioned over the lower teeth 2.2 to set the retaining device 1 in an engaged position 9. The spaced-apart arms 5.1 and 5.2 (preferably spring-loaded) extend from the grip retaining extensions 11.1 and 11.2, respectively to form a joint at base 6. Seated upon said base 6, are a clip 7 and clamp 8 having an opening 16 for receiving an endotracheal tube 4, such as a respiratory tube.

Q. Edwards

Fastening means 22 is attached to base 6 for releasably restraining the endotracheal tube 4 with respect to the spaced-apart dental arches 21.1 and 21.2. The spring loaded coils 20.1 and 20.2 applies a force onto dental arches 21.1 and 21.2, to remain in a spaced apart relationship accordingly whereby the retaining device 1 may perform the function of a bite block (not shown) by keeping the jaws of a patient in an open position.

The grip retaining extensions 11 can be any member having outer dimensions complementally shaped and large enough to grip onto the teeth 2 of a patient. Thus, preventing the endotracheal tube 4 to which the grip retaining extensions 11 are attached, from being inadvertently advanced into a patient's mouth after it has been properly positioned in the patient's airway 3. The shape of the grip retaining extensions 11 is critical. The grip retaining extensions 11, preferably is a platelike member having a flange 12 with a thickness that is small relative to its length and height. The grip retaining extensions 11, preferably has a channeled bend in a dental-arch-shape, forming a front and back wall for gripping therein the teeth 2 of a patient and if necessary, the surrounds of the bases of the teeth.

Ardayard

In one embodiment, the spaced-apart arms 5 extends from the grip retaining extensions 11 to form a joint at base 6. A clip 7 is seated upon base 6 with an opening 16 for receiving the endotracheal tube 4 through the opening 16. The opening 16 preferably has a diameter that is sufficiently large that the endotracheal tube 4 can easily pass through it. More preferably, the opening 16 allows the position of the endotracheal tube 4 with respect to the spaced-apart arms 5 and grip retaining extensions 11 to be adjusted without the exertion of much force. For example, the endotracheal tube 4 may fit loosely inside the opening 16.

In an alternative embodiment, a medical tube-retaining device 1 for an airway 3 may comprise first and second spaced-apart arms 5.1 and 5.2, spaced radially from at least one spring loaded coil 20.1, and at least one clip 7 mounted on a base 6 for engaging and holding the tube 4. Said spaced-apart arms are positioned to force a set of dental arches 21.1 and 21.2 away from each other for movement between an engaged and disengaged position.

The fastening means 22 secured to base 6, is used to releasably secure the endotracheal tube 4 to the clip 7. Preferably when the fastening means 22 is open, the attached endotracheal tube 4 can freely move in its longitudinal direction with respect to the clip 7 to enable the depth in the patient of the endotracheal tube 4 to be adjusted. Preferably when fastening means 22 is closed, the fastening means 22 engages the endotracheal tube 4 sufficiently tight to resist movement of the endotracheal tube 4 in its longitudinal direction with respect to the clip 7 without obstructing the endotracheal tube 4. This function of the fastening means 22 can be accomplished by a variety of structures.

Ar. L. L. L.

Alternatively, the fastening means 22 may be in the form of a clamp 8. The clamp 8 may have a closed position, and an open position. Preferably when the clamp 8 is open, the attached endotracheal tube 4 can freely move in its longitudinal direction with respect to the spaced-apart arms 5 to enable the depth in the patient of the endotracheal tube 4 to be adjusted. Preferably when the clamp 8 is closed, the clamp 8 engages the endotracheal tube 4 sufficiently tight to resist movement of the endotracheal tube 4 in its longitudinal direction with respect to the spaced-apart arms 5 without obstructing the endotracheal tube 4. This function of the clamp 8 can be accomplished by a variety of structures.

The clamp 8 is not restricted to one having pivotal jaws. For example, it may have jaws that translate rather than rotate with respect to each other to open and close the clamp 8. Alternatively, the clamp 8 may be replaced with a noose mechanism.

It should be appreciated that when the retaining device 1 is engaged, the first grip retaining extension 11.1 exerts a force in the direction of the upper teeth 2.1 due to the spring-loaded arm 5.1 and coil 20.1, while the second grip retaining extension 11.2 exerts a force in the opposite direction towards the lower teeth 2.2 of the patient due to spring-loaded arm 5.2 and coil 20.1, accordingly whereby the jaws of the patient are forced open. In this engaged position 9, the retaining device 1 can prevent the patient from obstructing the endotracheal tube 4 passing through the clip 7 and clamp 8.

In an alternative embodiment, the grip retaining extensions 11 may form a biting block where opposing sides of extensions 11.1 and 11.2 may be forced onto each other by the jaws of the patient and thus preventing the biting of the endotracheal tube 4 since the patient's teeth 2 will typically be able to exert a force on extensions 11. The illustrated retaining extensions 11 may have an enlarged portion such as an annular flange 12 to help retain the patient's incisors in the retaining extensions 11.

A further alternative embodiment includes additional clips and clamps to hold a second endotracheal tube. This additional clamp may be incorporated into clamp 8 by providing a second hump to form a second opening. Alternatively, the additional clamp may be a separate clamp identical to clamp 8.



The retaining device 1 may be made of a variety of materials, including both metals and plastics. It may be convenient if the grip retaining extensions 11 is made of a see-through material, such as a transparent plastic, to enable a patient's mouth to be readily observed during use of the retaining device to check for obstructions or contamination. The different components of the retaining device may be separately formed and then secured to each other, or a plurality of the components may be integrally formed with one another.

In the embodiments illustrated in Figures 1-3, the grip retaining extensions 11 and spaced apart arms 5 are integrally formed with one another preferably using a plastic molding process. It should be appreciated that the spaced-apart arms 5 may be slidably adjustable with reference to each other. Depending upon the materials of which these components are made, it is also possible to integrally form the clip 7 and clamp 8 with the dental arches 21 or spaced-apart arms 5.

When the distal end 5 has been properly positioned, the grip retaining extensions 11 may be forced over the patient's teeth 2, the fastening means 22 is opened and tube 4 is then slid along the length towards the patient's mouth until positioned. The fastening means 22 is then allowed to close around the endotracheal tube 4, preventing relative movement of the endotracheal tube 4 and the retaining device 1. The grip retaining extensions 11 is secured over the patient's teeth. The endotracheal tube 4 is now immobilized in a desired position with respect to the patient. If it is desired to either insert the endotracheal tube 4 farther into or partially remove from the patient's airway, then fastening means 22 can be released from the endotracheal tube 4. When fastening means 22 is open, the position of the endotracheal tube 4 in its longitudinal direction can be adjusted and guided by clip 7.

A retaining device according to the present invention is easy to use because grip retaining extensions 11, spaced-apart arms 5 and fastening means 22 for resisting movement of a respiratory tube, can be combined as one device. The clamp 8 or fastening means 22 can be operated with a single hand, so one person can readily adjust the retaining device.

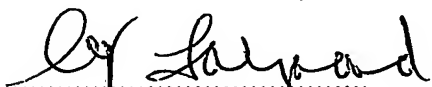
Ar. K. K. K.

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Although the present invention has been substantially as described with reference to the accompanying drawings and illustrated in detail, it is to be clearly understood that same is by way of illustration and example only, and is not taken by way of limitation. The spirit and scope of the invention are to be limited only by the terms and claims to be filed with the complete patent specification.

Thus, there is provided a medical tube retaining device that comprises a helpful means in all medical fields and applicable disciplines that is both cheaper and simpler to manufacture and offers performance advantages compared to conventional similar devices.

SIGNED at BLOENFENTEN on this 26 day of JUNE 2002.



As applicant and inventor

Dr André J. Taljaardt

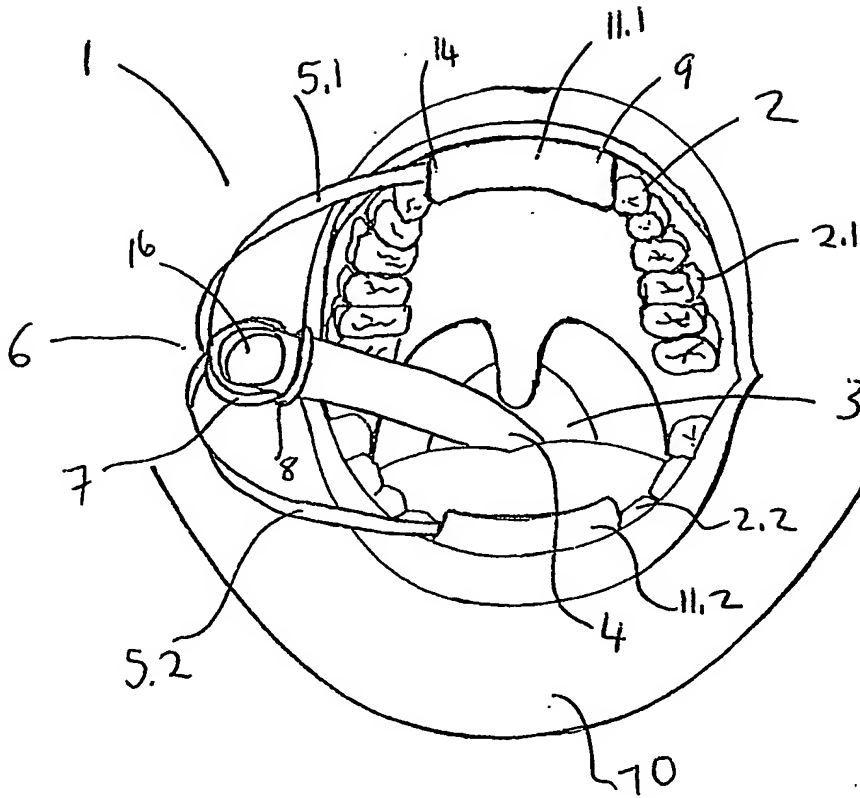


Figure 1

André J. Taljaardt
As applicant and inventor

Dr André J. Taljaardt

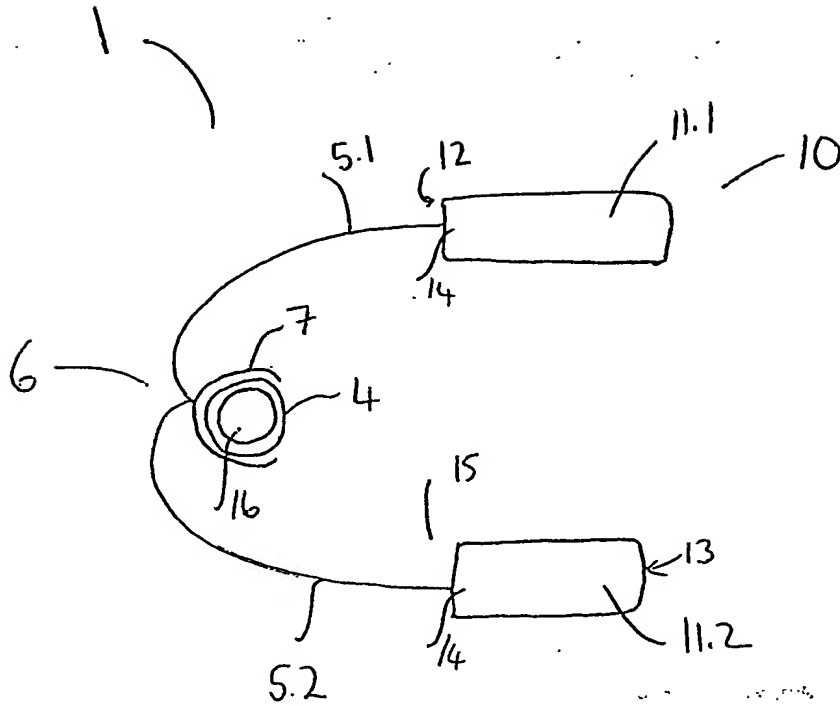


Figure 2

André J. Taljaardt
As applicant and inventor

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